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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,836	12/21/2001	Martina Elisabeth Werner	BT12 00103401(USP4) US	4194

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,836

Applicant(s)

WERNER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 December 2005 has been entered.

Status of the Claims

2. This action is in response to papers filed 7 December 2005 in which claims 70 and 78 were amended and claims 83-86 were added. New Claim 84 is previous Claim 82 written in independent format. Previously examined Claim 82 was indicated as allowable in the Final Office Action. However, following further search and consideration, the claims are no longer deemed free of the prior art.

The amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 13 April 2005, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 70-86 are under prosecution.

Claim Objections

3. Claim 70 is objected to because of the following informalities: Claim 70 has been improperly amended. Previously the last paragraph of the claim read "an active layer associated with said reflective layer". Applicant has replace phrase "associated with" with the

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phrase "adjacent to". The amended claim has "adjacent to" properly underlined, but does not cross out or recite the deleted phrase "associated with".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 78-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 78 has been amended to define the DNA immobilization as being "chemically bound" to the active layer. Applicant points to Fig. 14-17 and page 4, lines 17-20 for a supportive teaching of the immobilization. The cited passage is provided below.

The active layer is also utilized to anchor the capture DNA through interaction with a reactive group present on the capture DNA including, but not limited to, amino, thiol, carboxyl, aldehyde, and hydroxyl groups. Specific bead binding is achieved through DNA hybridization. Thus in a preferred embodiment of the present invention, the capture probes are connected to an amino (NH.sub.2) group, and the disc surface is coated with a layer of modified polystyrene, preferably polystyrene-co-maleic anhydride. The NH.sub.2 group binds (covalently) to the maleic anhydride, thereby attaching the DNA capture probe to the disc surface in a target or capture zone. Alternatively, the active layer may be formed from gold, activated glass, modified glass, or other modified media. The modified media includes anhydride groups, activated carboxylate groups, or carboxylic acid aldehyde groups.

The cited passage defines the immobilization using numerous reactive groups.

However, neither the passage nor the specification describes the meets and bounds of the

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newly claimed "chemically bound". Therefore, the newly claimed chemically bound constitutes new matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 70-77 and 84-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (U.S. Patent No. 6,143,247, issued 7 November 2000) and Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 70, Sheppard et al disclose a bio-disc comprising a circular substrate (i.e. disk platform, Column 10, lines 21-25), a reflective layer associated with the substrate (Column 10, line 64-Column 11, line 25), a plurality of target zones disposed in the reflective layer (Column 10, lines 64-67) and an active layer e.g. functional groups (Column 17, lines 20-54) adjacent to the reflective layer comprising immobilized binding partner and positioned to be contacted by interrogation beam through the target zones (Column 22, lines 1-67 and Fig. 6). Sheppard et al teaches the active layer adjacent to the reflective layer provides for automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36). Sheppard et al teach immobilized binding partners (Abstract), but do not teach DNA binding partners.

Wang et al disclose a similar bio-disc comprising a circular substrate (Fig. 3-5) a reflective layer associated with the substrate (Column 10, lines 38-40), a plurality of target zones disposed in the reflective layer (i.e. on the substrate, Column 3, lines 38-67) and an active layer i.e. chemically reactive group for binding DNA to the substrate, (Column 3, lines

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56-Column 4, line 9). While Wang does not teach the claimed functionality the illumination i.e. transmit interrogation beam, to reflect interrogation beam, permits interrogation. However, the illumination as illustrated in Fig. 7 clearly suggests interrogation beams as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the DNA binding partners of Wang et al to the bio-disc of Sheppard et al. One of ordinary skill in the art would have been motivated to do so based on the desire in the art for investigation of nucleic acid interactions as taught by Wang et al (Column 1, lines 24-40). Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the active layer-reflective layer arrangement of Sheppard et al to the bio-disc of Wang et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36).

Regarding Claim 71, Sheppard et al disclose the disc further comprising a fluidic circuit (Column 19, line 64-Column 20, line 12).

Regarding Claim 72, Sheppard et al disclose the disc wherein the fluidic circuit is formed from a membrane associated with the active layer (i.e. porous filter, Column 15, lines 5-12).

Regarding Claim 73, Sheppard et al disclose the porous filter associated with the active layer Column 15, lines 5-12). While they do not teach the filter is adhesive, they teach the filter increases surface area of the binding area. To increase the surface area, the filter must remain on the surface area during use. This clearly suggests there is some means (e.g. adhesive means) for maintaining the filter at the binding area. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use some adhesive means for maintaining the filter on the binding area for the benefit of maintaining the increased surface area during use (and spinning) as they desire.

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Regarding Claim 74, Sheppard et al disclose the bio-disc wherein the fluidic circuit comprises a flow channel (e.g. channel from inlet port #21 to binding chamber #24) and return channel (e.g. channel from binding chamber #24 to waste chamber #25).

Regarding Claim 75, Sheppard et al disclose the bio-disc wherein the return channel forms a "u" shape (i.e. channel from binding chamber #24 to waste chamber #25).

Regarding Claim 76, Sheppard et al disclose the bio-disc further comprising a cap portion (i.e. sealed chamber, Column 19, lines 32-51) providing an inlet port (Column 8, lines 16-25 and Fig. 2, #21).

Regarding Claim 77, Sheppard et al do not teach a second reflective section. However, Wang et al teach the second reflective portion (i.e. header, Column 10, lines 37-40) whereby analytes at the active sites are identified based on the information contained in the reflective header (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reflective header of Wang et al to the bio-disc of Sheppard et al for the expected benefit of providing means for analyte identification as taught by Wang et al (Abstract).

Regarding Claim 84, Sheppard et al disclose a bio-disc comprising a circular substrate (i.e. disk platform, Column 10, lines 21-25), a reflective layer associated with the substrate (Column 10, line 64-Column 11, line 25), a plurality of target zones disposed in the reflective layer (Column 10, lines 64-67) and an active layer e.g. functional groups (Column 17, lines 20-54) adjacent to the reflective layer comprising immobilized binding partner and positioned to be contacted by interrogation beam through the target zones (Column 22, lines 1-67 and Fig. 6). Sheppard et al teaches the active layer adjacent to the reflective layer provides for automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36).

Sheppard et al further teach the channels are connected by "valves" that require the application of pressure (via rotation of the disc) to induce fluid to flow from the channels (Column 20, lines 51-67). While Sheppard does not use the term "wall" as recited in the claim,

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their “valves” retain fluid and do open with pressure. This clearly suggests, “break away retaining” as, recited in the claim. Given the broadest reasonable interpretation of the claim, the retaining “valve” of Sheppard is encompassed by the break-away retaining wall of the claim. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a means for fluid communication between the channels by providing break-away retaining means as described by Sheppard.

Sheppard et al teach immobilized binding partners (Abstract), but do not teach DNA binding partners.

Wang et al disclose a similar bio-disc comprising a circular substrate (Fig. 3-5) a reflective layer associated with the substrate (Column 10, lines 38-40), a plurality of target zones disposed in the reflective layer (i.e. on the substrate, Column 3, lines 38-67) and an active layer i.e. chemically reactive group for binding DNA to the substrate, (Column 3, lines 56-Column 4, line 9). While Wang does not teach the claimed functionality the illumination i.e. transmit interrogation beam, to reflect interrogation beam, permits interrogation. However, the illumination as illustrated in Fig. 7 clearly suggests interrogation beams as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the DNA binding partners of Wang et al to the bio-disc of Sheppard et al. One of ordinary skill in the art would have been motivated to do so based on the desire in the art for investigation of nucleic acid interactions as taught by Wang et al (Column 1, lines 24-40). Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the active layer-reflective layer arrangement of Sheppard et al to the bio-disc of Wang et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36).

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Regarding Claim 85, Sheppard et al disclose the disc wherein the fluidic circuit is formed from a membrane associated with the active layer (i.e. porous filter, Column 15, lines 5-12).

Regarding Claim 86, Sheppard et al disclose the bio-disc further comprising a cap portion (i.e. sealed chamber, Column 19, lines 32-51) providing an inlet port (Column 8, lines 16-25 and Fig. 2, #21).

8. Claims 78, 79-81, 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al (U.S. Patent No. 4,390,499, issued 28 June 1983) in view of Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 78, Curtis discloses a device comprising a circular substrate (shaft #21) and a plurality of flow channels associated with the substrate, the channels divided by a break-away wall configured to break when the disc rotates at a predetermined speed (Column 5, lines 17-67). Curtis does not teach DNA chemically bound to the active layer. However, active layers having chemically bound DNA were well known in the art at the time the claimed invention was made as taught by Wang et al. Wang et al teach that chemically binding the DNA permits vigorous removal of non-specifically bound materials and enhances detection of higher stringency affinity interactions (Column 9, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chemically bound DNA of Wang et al to the bio-disc of Curtis for the expected benefit of detecting high affinity interactions as taught by Wang et al (Column 9, lines 61-67).

Regarding Claim 79, Curtis discloses the device comprising DNA immobilized on the active layer (blood serum components, Column 4, lines 48-52).

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Regarding Claim 80, Curtis discloses the channels are formed of a membrane (#17 and Column 5, lines 46-49).

Regarding Claim 81, Curtis discloses the device further comprising a cap #16 associated with an inlet port #15 (Fig. 2).

9. Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al (U.S. Patent No. 4,390,499, issued 28 June 1983) in view of Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) as applied to Claim 78 above and further in view of Sheppard, Jr. et al (U.S. Patent No. 6,143,247, issued 7 November 2000).

Regarding Claim 82, Sheppard et al disclose a bio-disc comprising a circular substrate (i.e. disk platform, Column 10, lines 21-25), a reflective layer associated with the substrate (Column 10, line 64-Column 11, line 25), a plurality of target zones disposed in the reflective layer (Column 10, lines 64-67) and an active layer e.g. functional groups (Column 17, lines 20-54) adjacent to the reflective layer comprising immobilized binding partner and positioned to be contacted by interrogation beam through the target zones (Column 22, lines 1-67 and Fig. 6). Sheppard et al teaches the active layer adjacent to the reflective layer provides for automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36).

Sheppard et al further teach the channels are connected by "valves" that require the application of pressure (via rotation of the disc) to induce fluid to flow from the channels (Column 20, lines 51-67). While Sheppard does not use the term "wall" as recited in the claim, their "valves" retain fluid and do open with pressure. This clearly suggests, "break away retaining" as, recited in the claim. Given the broadest reasonable interpretation of the claim, the retaining "valve" of Sheppard is encompassed by the break-away retaining wall of the claim. It would have been obvious to one of ordinary skill in the art at the time the claimed invention

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was made to provide a means for fluid communication between the channels by providing break-away retaining means as described by Sheppard.

Sheppard et al teach immobilized binding partners (Abstract), but do not teach DNA binding partners.

Wang et al disclose a similar bio-disc comprising a circular substrate (Fig. 3-5) a reflective layer associated with the substrate (Column 10, lines 38-40), a plurality of target zones disposed in the reflective layer (i.e. on the substrate, Column 3, lines 38-67) and an active layer i.e. chemically reactive group for binding DNA to the substrate, (Column 3, lines 56-Column 4, line 9). While Wang does not teach the claimed functionality the illumination i.e. transmit interrogation beam, to reflect interrogation beam, permits interrogation. However, the illumination as illustrated in Fig. 7 clearly suggests interrogation beams as claimed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the DNA binding partners of Wang et al to the bio-disc of Sheppard et al. One of ordinary skill in the art would have been motivated to do so based on the desire in the art for investigation of nucleic acid interactions as taught by Wang et al (Column 1, lines 24-40). Furthermore, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the active layer-reflective layer arrangement of Sheppard et al to the bio-disc of Wang et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of automated positioning of the interrogating light with submicron accuracy (Column 11, lines 33-36).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because

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the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 77-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8, 10-11 and 137-145 of copending Application No. 10/194,396. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to bio-disc comprising a circular substrate, a reflective layer (metal layer), an active layer and target zones. The claim sets merely differ in that the '396 claims are further drawn to a waste reservoir. However, the instant claim language "comprising" encompasses the additional element of the '396 claims. Therefore, the instantly claimed bio-disc is an obvious in view of the bio-disc of the '396 claim set.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
February 16, 2006